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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,009	11/21/2002	Ian Frazer	10905.0003.PCUS00	5472

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EXAMINER

SALIMI, ALI REZA

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 11/05/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/868,009

Applicant(s)

Frazer et al

Examiner

A. R. SALMI

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE Three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Aug 25, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-25, 32, and 33 is/are pending in the application.
- 4a) Of the above, claim(s) 6-10 and 15-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 11-14, 32, and 33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Nov 21, 2002 is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 11 6) ☐ Other:

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## **DETAILED ACTION**

### ***Election/Restriction***

Applicant's election with traverse of Group I in Paper No. 14 is acknowledged. The traversal is on the ground(s) that newly amended claim 1 does not read on Gupta et al because the newly amended claim 1 does not require early proteins. Applicants assert that in view of the amendment the invention of claim 1 is not known in the prior art and the restriction requirement should be withdrawn. This is not found persuasive because first the claims were only amended in view of the written restriction where the Office identified lack of contribution over the prior art by identifying Gupta et al. Still further, even after amending the claims the invention of Group I is not contributing anything novel over the prior art since teaching by Kirnbauer et al (Journal of Virology, 1993, Vol. 67, No. 12, pages 6929-6936) proves that the invention of Group I does not contribute over the teaching of prior art. In addition, with regard to selection of a particular papillomavirus Applicants argue that papilloma viruses belong to the same genus and various listed papillomas constitute a single invention. This argument is valid and the requirement is removed.

The requirement is still deemed proper and is therefore made FINAL.

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Claims 6-10, 15-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Groups, Applicant timely traversed the restriction (election) requirement in Paper No. 14.

**Applicants are reminded to cancel the claims to the non elected claims.**

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 11-14, 32, 33 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Jansen et al (US Patent No. 5,888,516).

The claims and teaching of the above cited patent meets the broad limitations of the claims 1-5, 11, 12, 32, 33. The above cited patent taught production of HPV vaccine by administering virus like particles wherein the particles are formed by HPV L1 or HPV L1 +L2 proteins. In

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addition, they taught HPV 6 and HPV 11 (see the claims 1-3). Moreover, Jansen et al taught the dosage range (see column 34 lines 11-13). The limitation of "PV L1 VLP and PV L1/L2 VLPs" have been noted by the Office, however, this limitation has no bearing on the patentability issue since the Applicants specification itself never combined the "PV L1 VLP and PV L1/L2 VLPs", and in addition there is no difference when one administers PV L1 VLP or PV L1/L2 VLPs. To substantiate the said remark see teaching by Peng et al (Pathology, 1993, Vol. 31, pp. 418-422), where they teach that there is no difference were observed between L1 and L1 + L2 VLPs. It is Office's position that the VLPs of Jansen et al would perform the same task as applicants' now claimed invention. It is noted that no-where in the Applicants' disclosure states that there were any differences observed with "PV L1 VLP and PV L1/L2 VLPs" as oppose to PV L1 VLP alone. As a matter of fact no such results are even present.

Moreover, applicants are directed to In re Cruciferous Sprout Litigation, 64 USPQ2d 1202 (CA FC 2002) wherein the Federal Circuit cited authority for the rule that, "a prior art reference may anticipate when the claim limitations not expressly found in that reference are nonetheless inherent in it." The court said, "While Brassica may have recognized something quite interesting about those sprouts, it simply has not invented anything new." This is the case here, while the Applicants may have "Observed" something interesting they have not have anything new.

Moreover, the claims that are not anticipated by the above cited patent are deemed be an obvious. The administration regiment and optimization as such is routine in this art. The limitations have

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been treated as a design choice unless the proof of criticality is proven. Therefore, the claimed invention is prima facie obvious absent unexpected results.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 11-14, 32, 33 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Jansen et al (US Patent No. 5,888,516).

The claims and teaching of the above cited patent meets the broad limitations of the claims 1-5, 11, 12, 32, 33. The above cited patent taught production of HPV vaccine by administering

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virus like particles wherein the particles are formed by HPV L1 or HPV L1 +L2 proteins. In addition, they taught HPV 6 and HPV 11 (see the claims 1-3). Moreover, Jansen et al taught the dosage range (see column 34 lines 11-13). The limitation of "PV L1 VLP and PV L1/L2 VLPs" have been noted by the Office, however, this limitation has no bearing on the patentability issue since the Applicants specification itself never combined the "PV L1 VLP and PV L1/L2 VLPs", and in addition there is no difference when one administers PV L1 VLP or PV L1/L2 VLPs, to substantiate the said remark see teaching by Peng et al (Pathology, 1999, Vol. 31, pp. 418-422), where they teach that there is no difference were observed between L1 and L1 + L2 VLPs. It is Office's position that the VLPs of Jansen et al would perform the same task as applicants' now claimed invention. It is noted that no-where in the Applicants' disclosure states that there were any differences observed with "PV L1 VLP and PV L1/L2 VLPs" as oppose to PV L1 VLP alone. As a matter of fact no such results are even present.

Moreover, applicants are directed to In re Cruciferous Sprout Litigation, 64 USPQ2d 1202 (CA FC 2002) wherein the Federal Circuit cited authority for the rule that, "a prior art reference may anticipate when the claim limitations not expressly found in that reference are nonetheless inherent in it." The court said, "While Brassica may have recognized something quite interesting about those sprouts, it simply has not invented anything new." This is the case here, while the Applicants may have "Observed" something interesting they have not have anything new.

Still further, the claims that are not anticipated by the above cited patent are deemed be an obvious. The administration regiment and optimization as such is routine in this art. The

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limitations have been treated as a design choice unless the proof of criticality is proven.

Therefore, the claimed invention is prima facie obvious absent unexpected results.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1-5 are rejected under 35 U.S.C. 102(e) as being anticipated by Zhao et al (US Patent No. 6,436,402 B1).

The claimed invention is anticipated by the teaching and claims of the above cited art (see claims 1-10). Moreover, applicants are directed to In re Cruciferous Sprout Litigation, 64 USPQ2d 1202 (CA FC 2002) wherein the Federal Circuit cited authority for the rule that, "a prior art reference may anticipate when the claim limitations not expressly found in that reference are nonetheless inherent in it." The court said, "While Brassica may have recognized something quite interesting about those sprouts, it simply has not invented anything new." This is the case here, while the Applicants may have "Observed" something interesting they have not have anything new.



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***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 11-14, 32, 33 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over by Kirnbauer et al (Journal of Virology, 1993, Vol. 67, No. 12, pp. 6929-6936).

The broad limitations of the claimed invention is clearly anticipated by the above cited art. Kirnbauer et al taught purification of HPV-6 L1, HPV-11 L1, and VLP-16 L1 (see Figure 2). In addition, they taught that HPV particles can be utilized in a vaccine composition (see page 6935, left column last paragraph). They also taught the cloning the HPV L1 in an expression vector and transforming cells (see page 6930 left column). The limitation of "PV L1 VLP and PV L1/L2 VLPs" have been noted by the Office, however, this limitation has no bearing on the patentability issue since the Applicants specification itself never combined the "PV L1 VLP and PV L1/L2 VLPs", and in addition there is no difference when one administers PV L1 VLP or PV L1/L2

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VLPs. To substantiate the said remark see teaching by Peng et al (Pathology, 1999, Vol. 31, pp. 418-422), where they teach that there is no difference were observed between L1 and L1 + L2 VLPs. It is Office's position that the VLPs of Jansen et al would perform the same task as applicants' now claimed invention. It is noted that no-where in the Applicants' disclosure states that there were any differences observed with "PV L1 VLP and PV L1/L2 VLPs" as oppose to PV L1 VLP alone. As a matter of fact no such results are even present.

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Still further, the claims that are not anticipated by the above cited patent are deemed be an obvious. The administration regiment and optimization as such is routine in this art. The limitations have been treated as a design choice unless the proof of criticality is proven. Therefore, the claimed invention is prima facie obvious absent unexpected results.

No claims are allowed.

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*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (703) 305-7136. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The Official fax number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

A. R. Salimi

11/3/2003

ALI R. SALIMI  
PRIMARY EXAMINER